

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Division of Patent Application Serial No. 09/265,670 of

EDMEADES

Atty. Ref.: 1430-272

Serial No. to be assigned

Group: 1743

Filed: August 29, 2001

Examiner:

For: COMPOUND AND ITS USE

\* \* \* \* \*

August 29, 2001

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Please amend the above-identified application as follows:

**IN THE SPECIFICATION**

Insert the following paragraph after the title.

This application is a division of Application No. 09/265,670, filed March 10, 1999, the entire content of which is hereby incorporated by reference in this application

Please replace the paragraph beginning at page 7, line 3, with the following rewritten paragraph:

(iv) estimating the intensity of any secondary spot obtained in the chromatogram of the sample solution, which corresponds in R<sub>f</sub> value to the reference marker, against the spot due to the reference marker in the chromatogram of the standard solution.

Please replace the paragraph beginning at page 7, line 16, with the following rewritten paragraph:

(iv) determining the main peak areas of each solution and calculating from these the content of the reference marker compound  
3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in the sample solution.

### **IN THE CLAIMS**

12. (New) A method of testing the stability to degradation of a solid pharmaceutical dosage form comprising lamotrigine, which method comprises assaying the said sample for the presence of  
3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one.

13. (New) A method of testing the stability to degradation of a solid pharmaceutical dosage form comprising lamotrigine, which method comprises using 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one as a reference marker.

14. (New) A method according to claim 12 for testing the stability to degradation of a solid pharmaceutical dosage form comprising lamotrigine, which includes the steps of:

(i) dissolving a sample of the dosage form in a solvent to produce a sample solution;

(ii) dissolving a sample of  
3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in a solvent to produce a reference marker standard solution;

(iii) subjecting the sample solution and the standard solution to thin layer chromatography to obtain a TLC chromatogram for each; and

(iv) estimating the intensity of any secondary spot obtained in the chromatogram of the sample solution, which corresponds in R<sub>f</sub> value to the reference marker, against the spot due to the reference marker in the chromatogram of the standard solution.

15. (New) A method according to claim 12 for testing the stability to degradation of a solid pharmaceutical dosage form comprising lamotrigine, which includes the steps of:

- (i) dissolving a sample of the dosage form in a solvent to produce one or more sample solutions;
- (ii) dissolving a sample of lamotrigine reference standard in a solvent to produce a standard solution;
- (iii) injecting the sample and standard solutions on to an HPLC column, and
- (iv) determining the main peak areas of each solution and calculating from these the content of the reference marker

3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in the sample solution.

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**REMARKS**

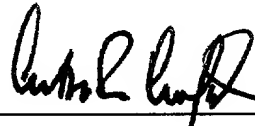
This application is directed to subject matter not included in the allowed claims in parent application Serial No. 09/265,670 filed March 10, 1999.

An examination on the merits taking into account the concurrently filed IDS is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION**

The paragraph beginning at page 7, line 3:

(iv) estimating the intensity of any secondary spot obtained in the chromatogram of the sample solution, which corresponds in R<sub>f</sub> value to the reference marker, against the spot due to the reference marker in the chromatogram of the standard solution.

The paragraph beginning at page 7, line 16:

(iv) determining the main peak areas of each solution and calculating from these the content of the reference marker compound  
3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in the [or each] sample solution.